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No. 90-1837

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

MINAS H. PAPAS, *et al.*,
Petitioners,

v.

ZOECON CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988), which vests the United States Environmental Protection Agency ("EPA") with comprehensive and exclusive authority to regulate the content of pesticide labeling, which defines labeling broadly and requires pesticide manufacturers to distribute their products only with EPA-approved labeling, which requires EPA to ensure that labeling contains warnings adequate to protect health and the environment, and which explicitly prohibits "any" state requirements for labeling "in addition to or different from" those imposed by EPA, preempts state law tort claims alleging that a pesticide manufacturer distributed its product with inadequate labeling or warnings.

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BRIEF IN OPPOSITION

The petition presents a federal preemption question arising entirely under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988). Respondent Zoecon Corporation [1] opposes certiorari because (i) there is no widespread split of appellate authority on the question of whether FIFRA preempts state law tort claims for inadequate pesticide labeling or warnings; (ii) the opinion of the U.S. Court of Appeals for the Eleventh Circuit correctly applies the principles of implied preemption and should conclusively resolve the question for federal and state trial courts; and (iii) the court's opinion, which affirms an interlocutory order granting Zoecon's motion for partial summary judgment with respect to petitioners' failure to

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[1] Zoecon has no subsidiaries which are not wholly owned. Its parent is Sandoz Corporation, a subsidiary of Sandoz Ltd.

warn claims, leaves petitioners free to pursue their other causes of action in the district court proceedings below.

COUNTER-STATEMENT OF THE CASE

A. EPA's Exclusive Control of Pesticide Label Warnings

FIFRA vests the United States Environmental Protection Agency ("EPA") with comprehensive and exclusive authority to regulate the content of a pesticide's labeling, including determining what product warnings pesticide manufacturers such as Zoecon should provide to pesticide applicators (i.e., users) such as petitioner Minas Papas.[2] EPA has the necessary scientific data, technical resources, expertise, experience, objectivity, and national perspective to determine which warnings and precautionary measures are warranted, and which are not, for each pesticide product.[3]

Section 24(b) of FIFRA broadly and explicitly prohibits "any" state law requirements for labeling "in ad-

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[2] FIFRA's definition of "labeling" encompasses "all labels and all other written, printed, or graphic matter . . . (A) accompanying the pesticide . . . at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide." 7 U.S.C. § 136(p)(2). The terms label and labeling are used interchangeably in this brief.

[3] EPA may register a pesticide only if it first determines that the product, when used in accordance with its labeling, will not cause "unreasonable adverse effects" to man or the environment. 7 U.S.C. §§ 136a(c)(5), 136(bb). In addition, EPA must determine that a pesticide's labeling complies with the other requirements of FIFRA, including that the product is not "misbranded." *See* 7 U.S.C. § 136(q); 40 C.F.R. § 152.112(f) (1990) (approval of registration). A pesticide is misbranded if, *inter alia*, "the label does not contain *a warning or caution statement* which may be necessary and if complied with . . . is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G) (emphasis added). A pesticide also is misbranded if "the labeling accompanying it does not contain *directions for use which . . . are adequate to protect health* and the environment." 7 U.S.C. § 136(q)(1)(F) (emphasis added).

dition to or different from" those imposed by EPA pursuant to FIFRA. 7 U.S.C. § 136v(b). Congress intended this provision "to completely preempt State authority in regard to labeling." H.R. Rep. No. 511, 92d Cong., 1st Sess. 16 (1971); *see also* S. Rep. No. 838, 92d Cong., 2d Sess. 30, *reprinted in* 1972 U.S. Code Cong. & Admin. News 3993, 4021. The Supreme Court's recent decision in *Wisconsin Public Intervenor v. Mortier*, 59 U.S.L.W. 4755 (U.S. June 21, 1991), which involved an entirely different FIFRA preemption issue (i.e., whether § 24(a) of FIFRA, 7 U.S.C. § 136v(a), preempts local governments from regulating pesticide use), makes it clear that labeling "fall[s] within an area that FIFRA's 'program' pre-empts." *Id.* at 4760. Indeed, as the Court observed, "FIFRA's historic focus [is] on labeling." *Id.* at 4759 (citing *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)).

By preempting state requirements for pesticide labeling, Congress has sought to achieve its objective of protecting health and the environment through nationally uniform labeling that is regulated solely by EPA. Congress reaffirmed this goal in 1988 by adding the heading "Uniformity" to FIFRA § 24(b). *See* Pub. L. No. 100-532, sec. 801(m)(2), 102 Stat. 2654, 2682 (1988).

Uniformity in labeling is critically important to fulfilling FIFRA's fundamental purpose, which is "to protect man and his environment." S. Rep. No. 838, 92d Cong., 2d Sess. 1, *reprinted in* 1972 U.S. Code Cong. & Admin. News 3993. Uniformity promotes applicator and public safety by enhancing user comprehension and avoiding confusion over conflicting or inconsistent label warnings and precautions. To achieve uniformity, EPA not only ensures that a particular manufacturer's pesticide product is labeled identically throughout the United States, but also that different manufacturers' brands of the same pesticide, alternative pesticides for the same uses, and pesticides posing similar risks, include label

warnings and precautionary measures which are identical or as consistent as possible.

The well-reasoned court of appeals decision which petitioners are asking this Court to review gives full force and effect to congressional intent. It recognizes that allowing juries to regulate pesticide labeling by means of state law damage awards "would destroy the uniformity that Congress and the EPA seeks to achieve in pesticide labeling," and thereby "disrupt the methods by which FIFRA protects man and the environment." *Papas v. Upjohn Co.*, 926 F.2d 1019, 1025, 1026 (11th Cir. 1991).

B. The Decision Below

Petitioner Minas Papas and his wife have filed a district court action for damages, alleging that his unfortunate health problems were caused in part by his occupational use of Paramite, an EPA-registered and labeled pesticide product manufactured and distributed by Zoecon. Their state law tort claims include—but are not limited to—theories that the EPA-regulated labeling accompanying Zoecon's product failed to provide adequate warnings. *See* Petition for a Writ of Certiorari ("Pet.") at 6 ("Common to each count, in addition to other asserted bases for relief, was the charge that the labels failed to adequately warn of [Paramite's] dangers and of steps that should be taken to avoid them"). The district court granted Zoecon's motion for partial summary judgment on the labeling claims, making it clear that its order did not extend to petitioners' non-warning related causes of action against Zoecon (i.e., manufacturing flaw, design defect). *See id.* Appendix ("Pet. App.") at 23-24.

In affirming the district court's order, the court of appeals held that "FIFRA impliedly preempts state common law tort suits against manufacturers of EPA-registered pesticides *to the extent that* such actions are based on claims of inadequate labeling." *Papas*, 926 F.2d

at 1026 (emphasis in original).[4] The court reviewed the "powerful limit on state power over labeling" embodied in FIFRA § 24(b), and found that "[u]nder FIFRA, the federal government—through the EPA—has the sole and exclusive right to regulate pesticide labels." *Id.* at 1023, 1024.

In addition to considering FIFRA § 24(b)'s express prohibition against state labeling requirements, the court examined the comprehensive manner in which EPA has regulated pesticide labeling, especially warnings, where the "desire for uniformity is particularly evident." *Id.* at 1024-25, 1025 n.6. On this basis, the court held "that the federal government has occupied the entire field of labeling regulation, leaving no room for the states to supplement federal law, even by means of state common law tort actions." *Id.* at 1025; *accord Fisher v. Chevron Chemical Co.*, 716 F. Supp. 1283, 1287 (W.D. Mo. 1989). In *Wisconsin Public Intervenor*, the Supreme Court indicated that while FIFRA does not occupy the field of pesticide regulation in general (or local use permitting in particular), FIFRA does occupy the field of pesticide labeling regulation. 59 U.S.L.W. at 4759.

As a separate basis for preemption, the court of appeals held that "jury awards of damages in such tort actions [for inadequate labeling] would result in direct conflict with federal law." *Papas*, 926 F.2d at 1025. The court found that "a jury determination . . . that a pesticide's labeling is inadequate results in a direct conflict with the EPA's determination that the labeling is adequate." *Id.*[5] As a result, labeling claims such as peti-

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[4] The court indicated that "[g]iven FIFRA's words and its legislative history, FIFRA may expressly preempt state common law actions of the kind before [the court]," but passed over the question of express preemption, concluding that "FIFRA impliedly preempts state common law tort actions based on labeling claims in several ways." *Id.* at 1023-24.

[5] The court found that "[s]uch a jury determination is also in direct conflict with the Congressional intent that *the EPA Ad-*

tioners' directly conflict with FIFRA § 24(b) and EPA's exclusive supervision of labeling.

The court also analyzed the effects of state law damage awards for supposedly inadequate pesticide labeling, and found that "allowing state common law tort suits for inadequate labeling would 'stand as an obstacle to the accomplishment and execution of the full objectives of Congress.'" *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). This is because the "case-by-case, state-by-state outside pressure on the regulatory process" resulting from "jury-found 'inadequacies' in labeling" would "hinder the development of an orderly, systematic, and uniform nationwide labeling scheme." *Papas*, 926 F.2d at 1026. The court concluded, therefore, that "[a] jury's imposition of damages in a state tort suit premised on labeling claims would disrupt the methods by which FIFRA protects man and the environment." *Id.*[6]

C. Petitioners' Misleading Statement of the Case

In downplaying the purpose and preemptive effect of FIFRA § 24(b), petitioners convey the erroneous impression that EPA plays little if any role in reviewing pesticide risks and regulating pesticide labeling. To the contrary, in implementing its "sole and exclusive right to regulate pesticide label[ing]. . . . EPA has regulated

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ministrator determine the reasonableness of the risks to man and the environment posed by pesticides, at least with respect to the labeling of pesticides." *Id.* (emphasis in original).

[6] The court also rejected petitioners' contention that there should be an exception to preemption where (unlike here) a manufacturer has failed to provide complete information to EPA. *Id.* at 1026 n.8. The court noted that "[g]iven the FIFRA regulatory scheme, it would be up to the EPA—and *not* a jury—to determine first (1) whether the information provided was incomplete or inaccurate; (2) whether the omitted information is significant enough to mandate a change in the label; and (3) how, if at all, the label should be corrected. *Id.* (emphasis in original); *see also Papas* dist. ct. slip op., Pet. App. at 22-23; *infra* at 9-10, 21-23.

almost every aspect of pesticide labeling." *Papas*, 926 F.2d at 1024.[7] To facilitate its labeling determinations, EPA has promulgated elaborate requirements for numerous types of state-of-the-art scientific studies, which it directs pesticide manufacturers to conduct in accordance with stringent protocols and submit within firm deadlines. *See* 7 U.S.C. § 136a(c)(2)(A), (B); 40 C.F.R. pt. 158 (1990) (listing dozens of required toxicology and other studies). EPA's Office of Pesticide Programs, which employs hundreds of scientists and has an annual budget of almost $100 million, exhaustively reviews these studies and data, and based on its review, determines precisely what warnings should accompany each pesticide product; specifies the exact wording and format to be utilized; and directs the pesticide manufacturer to comply. The manufacturer's duty is to distribute its pesticide product with the EPA-specified labeling. *See* 7 U.S.C. §§ 136a(a), 136a(c)(5)(B). To underscore this point, FIFRA makes it unlawful to add to or alter the EPA-approved labeling in any way. 7 U.S.C. § 136j(a)(2)(A).[8]

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[7] As the court of appeals noted, EPA has promulgated detailed regulations specifying the scope, content, wording, and format of pesticide labeling. *See* 40 C.F.R. pt. 156 (1990). A pesticide product cannot be registered under FIFRA unless its labeling complies with these regulations, and also with EPA's additional requirements, which encompass whatever specific warnings or precautionary statements the Agency determines are necessary to protect health and the environment in connection with use of the product. *See* 40 C.F.R. § 152.112(f). Because the ingredients, toxicity, and use patterns of each pesticide differ, EPA makes labeling determinations on a product-by-product basis. *See* 49 Fed. Reg. 37,960, 37,965 (1984) ("Because it is impossible to prescribe . . . exact statements for all combinations of ingredients, formulation types, and uses . . . . [t]he need for additional precautionary statements or modified ones [will] be determined on a case-by-case basis").

[8] Petitioners erroneously imply that EPA's review of a pesticide and its labeling is a one-time event. Pet. at 5 n.3. To the contrary, even after EPA approves the registration of a pesticide, it will instruct the registrant (i.e., manufacturer) to amend the pesticide's labeling to incorporate additional EPA-specified warnings, precau-

Petitioners' statement of the case also omits the undisputed material fact that Zoecon, as required by FIFRA, at all times distributed its Paramite pesticide product with the EPA-approved and required labeling. Furthermore, petitioners' statement is patently incorrect with respect to the regulatory status of Paramite, which is an EPA-registered pesticide (EPA Reg. No. 2724-169) labeled for external control of fleas, ticks, and scabies mites on dogs' skin. Since its introduction in 1978, Paramite and its labeling have been regulated solely by EPA pursuant to FIFRA.

Contrary to petitioners' assertions (Pet. at 4, 5 n.3), Paramite is not now, and never has been, registered with the Food and Drug Administration, or deemed to be a "new animal drug" under the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Petitioners' erroneous assertion that Paramite is regulated under FFDCA as well as FIFRA is rebutted by FIFRA's definition of "pesticide," which expressly excludes from the purview of FIFRA any "new animal drug" regulated under FFDCA. *See* 7 U.S.C. § 136(u); *see also* 21 U.S.C. § 321(q) (1988) (FFDCA definition of "pesticide chemical" incorporating FIFRA definition of "pesticide").[9]

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tionary statements, or other information when and if the Agency determines they are necessary. *See* 40 C.F.R. § 152.148(a). Furthermore, as part of the congressionally mandated FIFRA reregistration process, EPA reviews updated data needed to reassess whether a pesticide and its labeling continue to meet the statutory requirements for registration. *See* 7 U.S.C. § 136a-1; 40 C.F.R. § 152.144 ("the Agency may require a registrant to change a product's . . . labeling . . . to be reregistered and to maintain his registration in compliance with FIFRA"). Phosmet, the active ingredient in Paramite, along with most other pesticide active ingredients, is currently undergoing an exhaustive EPA reregistration review.

[9] Petitioners apparently are confusing Paramite, which has always been regulated exclusively as a pesticide pursuant to FIFRA, with GX-118, a Zoecon animal drug which contains the same active ingredient as Paramite, but has an entirely different purpose (treatment of internal grubs in beef cattle), method of application (spinal pour-on), and mode of action (internal/systemic).

Petitioners also erroneously assert that Paramite is "extremely similar" to, and performs "essentially the same function" as, Mitaban, the FFDCA-regulated animal drug distributed by Upjohn Co. which they allege was another cause of Mr. Papas' health problems. Pet. at 3, 27. Mitaban contains a different active ingredient than Paramite; its purpose is different (control of internal *Demodex canis* mites in dogs); and its mode of action is different (internal/systemic, not external).[10]

To compound their errors, petitioners grossly distort the facts regarding the toxicologically insignificant amount of benzene present as an *impurity* in one of Paramite's EPA-approved inert ingredients, Sure Sol 190, a solvent which was supplied to Zoecon by Koch Industries.[11] Benzene is of toxicological concern to EPA, and requires identification on a pesticide's label, *only* when it is deliberately added to a pesticide product as an inert ingredient, not where, as here, it is merely as an impurity associated with an inert. *See* 52 Fed. Reg. 13,305-307 (1987) (EPA policy statement on inerts which specifically addresses benzene and expressly excludes impurities). Petitioners' own toxicology expert confirmed in testimony at a preliminary hearing that the benzene in Paramite is not an inert ingredient, but merely an impurity (a side reaction product) created during manufacture of Sure Sol 190. Hearing Transcript at 12-13, *Papas v. Upjohn Co.*, No. 88-116-Civ-J-14 (M.D. Fla. Jan. 11, 1989) (Testimony of William L. Marcus). Nevertheless, petitioners repeatedly ignore or confuse this important distinction and refer to the minute

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[10] The district court's order does not address petitioners' claims against Upjohn Co., which is also a defendant in their suit.

[11] EPA's regulations define "inert ingredient" as "any substance . . . other than an active ingredient, which is *intentionally* included in the pesticide product." 40 C.F.R. § 158.153(f) (1990) (emphasis added). An "impurity" is "any substance . . . in a pesticide product *other than* an active ingredient or an inert ingredient, including . . . side reaction products [and] contaminants." *Id.* § 158.153(d) (emphasis added).

amount of benzene impurity in Paramite as if it were an (intentionally added) inert ingredient. *See, e.g.*, Pet. at 23-24 (referring to EPA's supposed "inability to adequately deal with inert ingredients (the culprit in the instant case)").

Petitioners' assertion that EPA lacked adequate information about Paramite because it was unaware of the benzene in Sure Sol 190 is incorrect. As a result of petitioners' allegations, Zoecon determined that the amount of benzene impurity present is less than 0.01% by weight (not 0.1% as petitioners assert). Zoecon *did* notify EPA, which confirmed that benzene impurities are frequently and unavoidably present in EPA-approved aromatic petroleum-based inert ingredients such as Sure Sol 190, and that such impurities do not warrant label warnings. For this reason, EPA does not require pesticide registrants to identify or submit data on impurities which are associated with (i.e., present in) inert ingredients, such as the innocuous benzene impurity associated with Koch's Sure Sol 190. *See* 40 C.F.R. § 158.155(e) (1990). Nor has EPA changed Paramite's labeling or taken any other regulatory action as a result of the benzene impurity in Sure Sol 190. Thus, there is no factual basis for petitioners' arguments regarding EPA's supposedly "inadequate" information.

Finally, it should be noted that petitioners' factual assertions regarding the nature, extent, and cause of Mr. Papas' health problems are all unproven allegations which, for the most part, are not even supported by the discovery that has been conducted at this early stage of the district court proceedings. Nor is petitioners' description of the proceedings below complete: Petitioners fail to inform the Court that they have initiated a separate district court action for damages against Koch, the supplier of the Sure Sol 190 inert ingredient which they allege caused Mr. Papas' health problems. *Papas v. Koch Refining Co.*, No. 90-790-Civ-J-16 (M.D. Fla. filed Sept. 6,

1990). That action, like petitioners' suit against Zoecon and Upjohn Co., asserts non-warning related causes of action as well as failure to warn theories. Thus, there is no basis for petitioners' assertions that the interlocutory decision of the court of appeals leaves them without a remedy.[12]

SUMMARY OF ARGUMENT

Although FIFRA § 24(b) was enacted almost twenty years ago, *Papas v. Upjohn Co.* is only the second federal appellate decision on FIFRA preemption of state law tort claims for inadequate labeling. The [illegible] decision, the District of Columbia Circuit's 1984 anti-preemption ruling in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), has been criticized with increasing frequency by federal and state trial courts. Furthermore, *Ferebee*'s flawed reasoning has been rejected in intervening Supreme Court cases such as *International Paper Co. v. Ouellette*, 479 U.S. 481 (1987). *Papas* will help to avert a future split of authority among trial courts by adding substantial weight and momentum to the judicial trend toward FIFRA preemption of jury-imposed requirements for pesticide labeling.

In holding that FIFRA impliedly preempts state law tort claims based on theories of inadequate labeling, the court of appeals in *Papas* adhered to traditional preemption principles and analysis. The court overcame any applicable presumptions against preemption by finding a clear and manifest congressional intent to preempt all state requirements for labeling.

Contrary to petitioners' assertions, the court of appeals did not err by rejecting their proposed exceptions to pre-

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[12] Zoecon's acquiescence to petitioners' application for an interlocutory appeal from the district court's order granting partial summary judgment obviously does not imply that the decision of the court of appeals warrants exercise of this Court's discretion to grant a writ of certiorari.

emption. Because petitioners are challenging the adequacy of labeling that EPA determined was adequate, their labeling-related claims fall squarely within FIFRA's regulatory scope and preemptive field. The court found that those claims would directly conflict with EPA's administration of FIFRA and its achievement of congressional objectives, rather than exert merely "indirect" regulatory pressure. Furthermore, based on EPA's comprehensive authority to regulate labeling, including its authority to specify and require pesticide manufacturers to submit data needed for determining appropriate warnings, the court correctly rejected petitioners' theory that preemption does not apply where EPA has "inadequate" data. Moreover, petitioners' arguments regarding inadequate data are hypothetical since there is no factual basis in this case for their contentions that EPA lacked data or information needed to regulate the labeling of Zoecon's Paramite pesticide product.

Petitioners' analogy to FFDCA is inapt because Paramite is not and never has been subject to regulation under that statute, and the Upjohn Co. animal drug which petitioners allege also caused Mr. Papas' health problems has a different purpose, mode of action, and active ingredient. In addition, petitioners have cited case law only under the drug provisions of FFDCA, which do not expressly prohibit state regulation of labeling as does FIFRA § 24(b). Petitioners fail to discuss the medical device provisions of FFDCA, 21 U.S.C. § 360k(a), which contain language virtually identical to FIFRA § 24(b), and under which there is a substantial body of case law holding that state law tort claims for inadequate labeling or warnings are preempted.

The court's decision does not leave petitioners without a remedy, since neither the district court nor the court of appeals held that petitioners' non-warning related claims are preempted. Further, the court's ruling does not affect petitioners' claims against Upjohn Co. or Koch Industries for the same alleged injuries.

Finally, there is no reason to hold the petition in abeyance pending the Court's decision in a preemption case involving the Federal Cigarette Labeling and Advertising Act, a statute which petitioners concede is significantly different from FIFRA. Preemption of state law tort claims for inadequate pesticide labeling does not depend on whether cigarette warning claims are preempted.

REASONS FOR DENYING THE WRIT

I. THERE IS NO WIDESPREAD SPLIT OF APPELLATE AUTHORITY

FIFRA preemption of state law tort claims for inadequate labeling has never ripened into a widespread controversy among appellate courts. During the two decades since enactment of FIFRA § 24(b), only two federal courts of appeals have ruled on the question: the D.C. Circuit in *Ferebee v. Chevron Chemical Co.*, and the Eleventh Circuit in the instant case.[13] No state courts of last resort have addressed the subject.

As petitioners acknowledge, the real split of authority has been among trial courts. That split was engendered by the flawed reasoning of the 1984 *Ferebee* decision, which numerous lower federal and state courts had squarely rejected well before the Eleventh Circuit's opinion in *Papas*.[14] A split of authority among lower courts

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[13] The Tenth Circuit is considering FIFRA preemption of labeling claims in *Arkansas-Platte & Gulf Partnership v. Dow Chemical Co.*, No. 91-1085 (10th Cir. appeal accepted Feb. 26, 1991). The appellee in that case has raised an issue as to whether the post-1972 (and current) version of FIFRA is applicable.

[14] *See, e.g., Hurt v. Dow Chemical Co.*, No. 90-0783-C(3) (E.D. Mo. Sept. 28, 1990); *Kennan v. Dow Chemical Co.*, 717 F. Supp. 799 (M.D. Fla. 1989); *Fisher v. Chevron Chemical Co.*, 716 F. Supp. 1283 (W.D. Mo. 1989); *Herr v. Carolina Log Buildings, Inc.*, No. EV 85-262-C (S.D. Ind. Sept. 22, 1989); *Watson v. Orkin Exterminating Co.*, No. JFM-88-2427 (D. Md. Nov. 8, 1988); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404 (E.D. Mich. 1987); *Bolduc v.*

normally is not sufficient reason for the Supreme Court to exercise its discretion to grant certiorari. *See* S. Ct. R. 10.

Rather than create confusion or unpredictability, which petitioners assert already existed in the wake of *Ferebee*, the *Papas* decision adds substantial weight and momentum to the judicial trend among trial courts toward FIFRA preemption of state law tort claims for inadequate labeling. *Papas* thereby will help diminish any further uncertainty as to whether pesticide manufacturers can be held liable under state tort law for distributing their products with labeling that EPA has determined is adequate and requires them to utilize. Indeed, the impact of *Papas* already has been felt: Trial courts around the country have begun to adopt its conclusions and reasoning.[15]

The Supreme Court's intervening decisions also have reduced *Ferebee*'s credibility. For example, *Ferebee* is

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Chemed Corp., No. 43-94-55 (Cal. Super. Ct. Orange Cty. Apr. 10, 1989), *aff'd on other grounds*, No. G008338 (Cal. Ct. App. Sept. 24, 1990); *Lopez v. Chevron Chemical Co.*, No. 89272 (Cal. Super. Ct. Ventura Cty. Oct. 25, 1988); *Oppermann v. Stevens*, No. 88CV1192 (Colo. Dist. Ct. Boulder Cty. June 1, 1990); *Begley v. Truly Nolen Exterminating, Inc.*, No. 90-870 (Fla. Dist. Ct. App. 3d Dist. Feb. 5, 1991).

[15] *See, e.g., Mims v. Mobay Corp.*, No. M-88-157 (S.D. Tex. June 13, 1991) ("The Court is persuaded by the reasoning of the Eleventh Circuit in *Papas v. Upjohn Co.* . . . and elects to follow that decision"); *Southern Colorado Farms, Inc. v. Green*, No. 88 CV 40, slip op. at 4 (Colo. Dist. Ct. Saguache Cty. June 7, 1991) ("The Court finds persuasive and hereby adopts the reasoning and holding of the U.S. Court of Appeals for the Eleventh Circuit in *Papas v. Upjohn Co.*"); *Brennan v. Dow Chemical Co.*, No. CL-90-8882 AO (Fla. Cir. Ct. Palm Beach Cty. June 3, 1991); *Abelman v. Velsicol Chemical Corp.*, Civ. No. 12611, slip op. at 26 (Md. Cir. Ct. Montgomery Cty. May 17, 1991) ("This Court finds the reasoning of the *Papas* Court persuasive for the reasons stated therein"); *Davidson v. Velsicol Chemical Corp.*, No. A-246535 (Nev. Dist. Ct. Clark Cty. Apr. 5, 1991).

premised on the erroneous notion that because a damage award for inadequate labeling is not "a direct regulatory command" to change the label, a pesticide manufacturer may prefer to choose leaving the label the way it is, while "simultaneously paying damages to successful tort plaintiffs" in future suits. *Ferebee*, 736 F.2d at 1541; *see* Pet. at 22-23. In *International Paper Co. v. Ouellette*, 479 U.S. at 495, however, which petitioners fail to cite, this Court confirmed that such a "choice of reaction" is illusory.

The Court held in *International Paper Co. v. Ouellette* that the Clean Water Act, a federal environmental protection statute, preempted certain state law tort suits against manufacturers which comply with EPA's regulatory requirements because "the threat of legal . . . penalties . . . would compel the [manufacturer] to adopt different . . . standards . . . from those approved by the EPA." The Court explained that "[t]he inevitable result of such suits would be that . . . States could do indirectly what they could not do directly—regulate." *Id.* "It would be extraordinary for Congress, after devising an elaborate permit system that sets clear standards, to tolerate common-law suits that have the potential to undermine this regulatory structure." *Id.* at 497. *Ferebee* failed to take into account such interference "with the methods by which the federal statute was designed to reach [its] goal." *Id.* at 494; *see Papas*, 926 F.2d at 1021-22, 1025-26.

More recently, in the labor law context, the Court has recognized that state law tort suits are preempted where they "would subject [federally regulated companies] to burdens not unlike those that Congress sought to foreclose," particularly where "courts, exercising their common law powers, might develop different substantive standards applicable to the same . . . conduct, requiring the tailoring of . . . conduct to the peculiarities of the law of each jurisdiction." *Ingersoll-Rand Co. v. McClen-*

don, 111 S. Ct. 478, 484 (1990) (ERISA preempted employee's state law wrongful discharge claim). "Such an outcome is fundamentally at odds with the goal of uniformity that Congress sought to implement." *Id.*; *see also International Union, UAW v. Johnson Controls, Inc.*, 111 S. Ct. 1196, 1209 (1911) (quoting *Farmers Union v. WDAY, Inc.*, 360 U.S. 525, 531 (1959)) (dicta in employee sex discrimination suit that allowing state law tort liability for complying with federal requirements "would sanction the unconscionable result of permitting civil . . . liability to be imposed for the very conduct the [federal] statute demands of the licensee").[16] Again, the *Ferebee* decision ignored such considerations by failing to recognize the deleterious effects that damage awards from tort claims for inadequate labeling would have on EPA's accomplishment and execution of congressional objectives, especially Congress' goal of uniform national labeling that is regulated exclusively by EPA pursuant to FIFRA's standards.

Thus, while *Papas* technically created a split of authority between two federal circuits, it is a lopsided split that will become even less viable as additional courts have the opportunity to consider and adopt *Papas* after comparing it with *Ferebee*.

II. THE COURT OF APPEALS CORRECTLY APPLIED THE PRINCIPLES OF IMPLIED PREEMPTION

None of petitioners' contentions that the *Papas* opinion conflicts with the analytical framework for preemption analysis or deviates from preemption principles has merit or is a basis for granting a writ of certiorari in this case.

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[16] It is well established that a state cannot impose common law damages upon corporations for doing what a federal act or regulation "authorized them to do." *Chicago & N.W. Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 318 (1981); *see also Fidelity Federal Savings & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 155 (1982).

A. The Court Adhered to Standard Preemption Analysis and Principles

The court's opinion presents a traditional preemption analysis that follows well-established principles. It begins by summarizing the various ways that federal law can preempt state law, and explains that "[t]he principle of implied preemption 'applies . . . whether the state law is rooted in a statute, regulation, or common law rule.'" 926 F.2d at 1021-22 (quoting *Taylor v. General Motors Corp.*, 875 F.2d 816, 826 (11th Cir. 1989) (citations omitted), *cert. denied*, 110 S. Ct. 1781 (1990)). The court emphasizes that "[a] state law—even if it has the same ultimate goal as a federal law—may stand as an obstacle to the full implementation of a federal law and therefore be preempted 'if it interferes with the methods by which the federal statute was designed to reach this goal.'" 926 F.2d at 1021-22 (quoting *International Paper Co. v. Ouellette*, 479 U.S. at 494).

Further, the court explained that "[t]he critical question in considering whether state law is preempted by federal law is Congressional intent—that is, 'whether Congress intended that federal regulation supersede state law.'" 926 F.2d at 1022 (quoting *Louisiana Public Service Commission v. FCC*, 476 U.S. 355, 369 (1986)). "'[I]n implied preemption analysis it is possible to infer preemptive intent solely from effects': even if statutory language or legislative history is unclear, federal law pr mpts state law if 'the ordinary application of the two creates a conflict.'" 926 F.2d at 1022 (quoting *Taylor*, 875 F.2d at 826).

The court then discusses FIFRA's statutory scheme, emphasizing that in § 24, 7 U.S.C. § 136v, "Congress delineated the extent to which the states could regulate pesticides," allowing states "to impose stricter regulation on pesticide *use*," but "completely preempt[ing] State authority in regard to labeling." *Id.* at 1023 (quoting S. Rep. No. 92-838 at 30, *reprinted in* 1972 U.S. Code

Cong. & Admin. News at 4021 (emphasis in original); H.R. Rep. No. 92-511 at 16); *accord Wisconsin Public Intervenor*, 59 U.S.L.W. at 4759-60; *New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115, 118 (2d Cir. 1989).[17]

The court indicates that given its "words and its legislative history, FIFRA may expressly preempt state common law actions of the kind before us." Nevertheless, the court exercises caution by passing over the question of express preemption, and instead, considers "whether federal preemption of state common law tort claims based on labeling deficiencies can be inferred." *Papas*, 926 F.2d at 1023-24.

The court begins its implied preemption analysis by explaining that under FIFRA, EPA "has the sole and exclusive right" to regulate pesticide labeling, and by describing the comprehensive way that EPA has implemented this authority, especially with respect to warnings. *Id.* at 1024. As discussed above, the court finds that "FIFRA impliedly preempts state common law tort actions based on labeling claims in several ways." *Id.* First, the court holds that pursuant to FIFRA § 24(b), the federal government has occupied the field of pesticide

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[17] Petitioners have misread the *New York State Pesticide Coalition* case, which merely held that FIFRA does not preempt state agencies from promulgating regulations requiring commercial applicators to provide certain public notifications about their pesticide application activities. There is no suggestion in the case that pesticide manufacturers such as Zoecon, which comply with EPA labeling requirements, can or should be subject to additional labeling requirements or notification duties imposed by state law, much less through common law tort actions. Indeed, the Second Circuit explained that FIFRA § 24(b) places labeling within "EPA's *exclusive supervision*"; that "FIFRA 'labeling' is designed to be read and followed by the *end user*" (e.g., petitioner Papas); and that "FIFRA's prohibition of state labeling 'in addition to or different from' that approved by the EPA has as 'its main focus . . . *preserving the force of the information contained in the FIFRA label.*'" 874 F.2d at 118, 119 (emphasis added).

labeling regulation, leaving no room for state common law tort actions based on labeling claims. *Id.* at 1024-25. Second, the court holds that damage awards in such tort actions would directly conflict with federal law by conflicting with EPA's determination pursuant to FIFRA that a pesticide's labeling is adequate, and by interfering with EPA's achievement of labeling uniformity, thereby standing as an obstacle to accomplishment and execution of Congress' objectives. *Id.* at 1025-26. The court concludes that state common law tort claims for inadequate labeling are preempted because they would violate FIFRA and congressional intent by imposing requirements for labeling pesticides. *Id.* at 1026.[18]

B. The Court's Opinion Overcomes Any Applicable Presumptions Against Preemption

Petitioners transform the general presumption against preemption into an absolute bar, and then assert that the court of appeals has disregarded it. Pet. at 18-20. To the contrary, the court's opinion goes to great lengths to show that Congress' clear and manifest purpose was to preempt all state requirements for labeling so that EPA alone could regulate labeling and thereby protect health by achieving national uniformity. The court, therefore, has made all the findings requisite to overcoming any applicable presumptions against preemption. *See Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). By claiming that "uniformity of labeling was not particularly important to Congress," petitioners demonstrate it is they who have "failed to take notice of Congress's overriding intent." Pet. at 22; *see Papas*, 926 F.2d at 1026 (EPA evaluates toxicological data "to achieve the protection of 'man and his environment' through a labeling

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[18] As previously noted, the court also finds that there is no exception where (unlike here) a pesticide manufacturer has failed to provide complete information to EPA. *Id.* at 1026 n.8; *see supra* at 6 n.6.

system that is uniform and consistent across the broad spectrum of pesticides").[19]

C. This Is Not a Case Involving "Indirect" or "Incidental" Regulatory Pressure

Petitioners suggest that their state law tort claims challenging the adequacy of EPA-regulated, approved and mandated labeling would exert only "indirect regulatory pressure," and as a result, should not be preempted. Pet. at 19-21. As the court of appeals recognized, however, there is nothing "indirect" about the way in which petitioners' claims "would disrupt the methods by which FIFRA protects man and the environment." *Papas*, 926 F.2d at 1026. It is well settled that the "imposition of damages under state tort law has long been held to be a form of state regulation subject to the supremacy clause." *Id.* (quoting *Taylor v. General Motors Corp.*, 875 F.2d at 824 n.16); *see also Ingersoll-Rand Co. v. McClendon*, 111 S. Ct. at 484; *International Paper Co. v. Ouellette*, 479 U.S. at 495; *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959).

The cases cited by petitioners (Pet. at 19, 21) do not help their cause. In two of the cases the Court found that the subject matter of the tort claim, and thus its regulatory effect, was not sufficiently related to the regulatory purpose of the federal statute to fall within its preemptive field. *See English v. General Electric Co.*, 110 S. Ct. 2270, 2278 (1990) (employee's claim for nu-

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[19] Petitioners' assertion that FIFRA "does not preclude manufacturers of identical products from using vastly different labels" is simply incorrect. Pet. at 22. As the court of appeals explained, "[o]ne of the EPA's objectives in its labeling regulations is the uniformity of labeling across the nation and among (1) different brands of the same pesticide, (2) different pesticides performing the same function, and (3) different pesticides posing the same or similar risks to health and the environment." *Papas*, 926 F.2d at 1025 (citing 40 C.F.R. pt. 156).

clear facility's intentional infliction of emotional distress due to employment termination was not preempted by federal statute intended to regulate nuclear safety); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988) (claim for personal injuries due to accidental fall from scaffolding caused by nuclear facility's breach of state scaffolding safety regulations was not preempted by federal statute intended to regulate nuclear safety).

Unlike the situation in each of those cases, where the subject matter of the tort claim was only on the fringes of the federal statute's regulatory field, petitioners' claims for injuries allegedly due to "inadequate" EPA-regulated and approved pesticide labeling fall squarely within one of FIFRA's principal regulatory purposes—regulation of pesticide labeling. Accordingly, this is not a case of "indirect" or "incidental" regulatory pressure enabling petitioners to circumvent preemption.[20]

D. There Is No Exception to Preemption in this Case for Allegedly "Inadequate" Data

Petitioners argue that preemption should not apply where EPA has approved a label "on the basis of false or inaccurate information." Pet. at 25. Yet, it has not been established in this case that EPA had "false or inaccurate" information, or lacked any data or information that it needed to regulate Paramite's labeling. Indeed, petitioners' assertion that "EPA was never informed that Zoecon's product contained benzene in extremely dangerous quantities" is what is false and misleading. Pet. at 26.

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[20] The third case cited by petitioners is distinguishable because Congress specifically provided for the type of claim that was brought. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251-52, 256 (1983) (wrongful death claim for punitive damages due to radiation injuries at nuclear facility was not preempted by federal nuclear safety regulatory statute because Congress incorporated into statute indemnification scheme for such claims, thereby demonstrating its intent that such claims could be brought).

As Zoecon explains in its Counter-Statement of the Case, a minute and toxicologically insignificant amount of benzene was present as an unavoidable impurity in Sure Sol 190, one of Paramite's EPA-approved inert ingredients; Zoecon informed EPA of the presence of this impurity; EPA confirmed it is aware that benzene impurities are unavoidably present in aromatic petroleum-based inert ingredients such as Sure Sol 190; EPA also confirmed that it is not toxicologically concerned about benzene when it is present as an impurity in an inert; and as a result, EPA does not require pesticide manufacturers to identify or submit information regarding benzene impurities, and does not require pesticide labeling to identify or provide warnings regarding benzene impurities. See *supra* at 9-10. Thus, petitioners' arguments regarding a supposed exception to preemption when EPA lacks adequate data are completely hypothetical and have no applicability to this case.

Furthermore, as the court of appeals noted, it is EPA's function under FIFRA, not a jury's, to determine whether EPA possesses adequate data. *See Papas*, 926 F.2d at 1026 n.8; *supra* at 6 n.6.[21] The court refused to recognize an exception to preemption where, as here, "the federal statute involved explicitly prohibits state regulation of labeling." *Id.* For this reason, the court rejected the holding of *Hurley v. Lederle Laboratories*, 863 F.2d

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[21] FIFRA § 6(a)(2) provides that "[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator." 7 U.S.C. § 136d(a)(2). EPA has indicated that this duty to report adverse effects information encompasses information that would affect its determinations as to necessary label precautions. *See* 40 C.F.R. § 153.78(a)(2) (1990); 43 Fed. Reg. 37,611, 37,613 (1978). FIFRA makes it unlawful for a pesticide registrant to fail to submit data required by § 6(a)(2). 7 U.S.C. § 136j(a)(2)(B)(ii).

1173, 1179 (5th Cir. 1988) "[t]o the extent that *Hurley* purports to recognize an exception." *Id.*[22]

E. Petitioners Cite the Wrong FFDCA Case Law in Making Their Analogy to FIFRA

Paramite, the EPA-registered and labeled pesticide product involved in this case, is not and never has been regulated under FFDCA. See *supra* at 8. Nor is Zoecon's Paramite the same as or similar to Upjohn's Mitaban, which has a different purpose, mode of action, and active ingredient, and unlike Paramite, is regulated as an animal drug under FFDCA. See *supra* at 9. Nevertheless, petitioners repeatedly and erroneously assert that Paramite is subject to both statutes (which FIFRA § 2(u), 7 U.S.C. § 136(u), precludes), and on that basis, attempt to compare FIFRA with FFDCA, which they contend does not preempt claims for inadequate drug warnings. Pet. at 4-5, 5 n.3, 6 n.4, 27-28.[23]

Petitioners' analogy to FFDCA is garbled. The "vast body" of FFDCA case law to which petitioners refer involves FFDCA's drug provisions, which differ signifi-

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[22] *Hurley* held that state law tort claims for inadequate warnings regarding FDA-regulated vaccines are preempted "assuming that the FDA has processed all of the relevant and available information on which to base the warning." *Id.* The court premised this holding on its understanding that FDA is a "partially passive agency" because it merely reviews whatever data are submitted by manufacturers, rather than specifying to manufacturers what data it needs to determine proper warnings. *Id.* The situation is entirely different under FIFRA, pursuant to which EPA plays an active and pervasive role, not only by intensively reviewing data submitted by manufacturers and determining what label warnings should be given, but also by specifying in detail what scientific data pesticide manufacturers must submit in order to obtain and maintain pesticide registrations. *See* 40 C.F.R. pt. 158.

[23] Petitioners' citation of *Wells v. Ortho-Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986), is misplaced, as that case did not involve preemption, and the court's citation of *Ferebee* was in an evidentiary context.

cantly from FIFRA since they do not expressly prohibit imposition of state requirements for labeling. Instead, petitioners should have cited the case law under the medical device provisions of FFDCA, which are the FFDCA provisions containing language virtually identical to FIFRA § 24(b).

Section 521 of the Medical Device Amendments to FFDCA provides in pertinent part that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) *which is different from, or in addition to,* any requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a) (1988) (emphasis added).[24] A vast body of FFDCA case law holds that this provision preempts state law tort claims for inadequate labeling or warnings in connection with distribution of FFDCA-regulated medical devices (e.g., tampons). *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 n.22 (5th Cir. 1989) (collecting cases); *Berger v. Personal Products, Inc.*, 115 Wash. 2d 267, 797 P.2d 1148, 1150 n.9 (1990) (collecting cases), *cert. denied*, 111 S. Ct. 1584 (1991). Thus, the FFDCA provisions with language similar to FIFRA § 24(b) are consistent with and *support* the holding of the *Papas* decision.[25]

F. The Court's Decision Does Not Leave Petitioners Without a Remedy

There is no principle that preemption is inapplicable where it deprives a plaintiff of legal remedies. "'[T]he relative importance to the State of its own law is not

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[24] States or political subdivisions may avoid preemption by applying to FDA for a specific exemption pursuant to 21 U.S.C. § 360k(b).

[25] In light of the FFDCA case law which overwhelmingly upholds preemption, there is no basis for petitioners' speculation that Upjohn believed Zoecon's FIFRA preemption motion would be "futile." Pet. at 6 n.4.

material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'" *Felder v. Casey*, 487 U.S. 131, 138 (1988) (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)). Thus, even "[a] state law action which shares the same purpose as the federal law in question is preempted if it attempts to achieve that purpose by a method which interferes with the federal methods." *Papas*, 926 F.2d at 1026.

Nevertheless, the court's decision does not leave the petitioners (or as they assert, other pesticide "victims") without a state law remedy. As Zoecon explains in its Counter-Statement of the Case, the court of appeals affirmed the district court's grant of *partial* summary judgment, as to warning-related claims only. See *supra* at 4-5. The district court's order makes it clear that petitioners are not preempted from proceeding against Zoecon on non-warning related manufacturing flaw and design defect product liability claims. *See* Pet. App. at 23-24. Furthermore, the district court's order does not apply to petitioners' claims against Upjohn Co., or to petitioners' separate suit against Koch, Zoecon's supplier of Sure Sol 190. Therefore, if certiorari is denied, petitioners will be free to proceed with their other, non-preempted claims.

III. THE PETITION SHOULD NOT BE HELD IN ABEYANCE

Petitioners request in the alternative that their petition be held in abeyance pending the Court's decision in *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541 (3d Cir. 1990), *cert. granted*, 111 S. Ct. 1386 (1991). Respondent Zoecon opposes this request because FIFRA preempts claims for inadequate pesticide labeling regardless of whether the Federal Cigarette Labeling and Advertising Act preempts cigarette failure to warn suits.

As petitioners concede, there are "significant differences between the Cigarette Act and FIFRA." Pet. at 13. For example, FIFRA, unlike the Cigarette Act, prohibits manufacturers from providing warnings that the federal government has not determined are warranted and approved. *See* 7 U.S.C. § 136j(a)(2)(A). Furthermore, FIFRA, unlike the Cigarette Act, incorporates a risk-benefit standard, recognizing that availability and use of pesticides confers substantial benefits upon society, including protecting public health and safety, the natural environment, and the agricultural economy. *See* 7 U.S.C. § 136(j), (x), (bb).

Petitioners' assertion that the argument for FIFRA preemption is "less compelling" than for Cigarette Act preemption lacks foundation. Pet. at 13. Their reliance on a lone footnote in a cigarette decision does not make their case. *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 629 n.3 (1st Cir. 1987). That footnote misperceives EPA's total control over pesticide label warnings; confuses the states' authority to regulate pesticide use under FIFRA § 24(a) with the explicit prohibition in FIFRA § 24(b) against state regulation of labeling; and draws "a distinction without significance" regarding incorporation of required cigarette warnings into the text of the Cigarette Act. *Fisher v. Chevron Chemical Co.*, 716 F. Supp. 1283, 1289 (W.D. Mo. 1989).

Regarding the final point, the footnote in *Palmer* fails to recognize that compared to pesticides, cigarettes are a relatively uniform product with relatively uniform risks; it would be impractical to specify in the text of FIFRA precise warning language for hundreds of currently registered pesticide products, which differ significantly from each other in toxicology and environmental behavior. Instead, through FIFRA, Congress assigned the task of regulating pesticide label warnings to EPA alone. That

is why the Eleventh Circuit was correct in holding that FIFRA preempts petitioners' labeling-related claims.[26]

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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Dated: June 28, 1991

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[26] Except for *Cipollone*, where the respondent concurred in the certiorari petition, the Court has repeatedly denied review of product liability cases involving the question of federal preemption of state law tort claims. *See, e.g., Berger v. Personal Products, Inc.*, 115 Wash. 2d 267, 797 P.2d 1148 (1990), *cert. denied*, 111 S. Ct. 1584 (1991) (tampon warnings); *Graham v. Wyeth Laboratories*, 906 F.2d 1399 (10th Cir.), *cert. denied*, 111 S. Ct. 511 (1990) (DTP vaccine warnings); *Pokorny v. Ford Motor Co.*, 902 F.2d 1116 (3d Cir.), *cert. denied*, 111 S. Ct. 147 (1990) (automobile air bags).